UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MARYLAND

United States ex rel. William Morehead & Rhonda Keyes-Morehead
c/o The Law Office of Christopher M. Young
700 12th Street, Ste 700, NW
Washington, DC 20005
Plaintiffs-Relators

BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA

c/o Erek L. Barron
United States Attorney, District of Maryland
United States Attorney's Office
36 S. Charles Street 4th Fl.
Baltimore, MD 21201

And

Merrick Garland
Attorney General of the United States
Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Plaintiffs,

Centers for Medicare and Medicaid Services

and

North Carolina Department of Health and Human Services

CHIQUITA BROOKS-LASURE in her official capacity as Administrator of the Centers for Medicare and Medicaid Services;

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COMPLIANT
(JURY TRIAL DEMANDED)

and)
)
KODY KINSLEY in his official) **UNDER SEAL**
Capacity as Secretary of Health and Human)
Services for the State of North Carolina)
Centers for Medicare and Medicaid Services)
North Carolina Department of Health and)
Human Services)
)
and)
)
Dr. Mandy Cohen)
)
and)
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Dr. Cardra E. Burns)
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and)
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Dave Richard)
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and)
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Jay Ludlam)
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and)
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Melanie Bush)
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and)
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Sandra Terrell)
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and)
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Sam Gibbs)
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and)
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Steve Tedder)
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and)
)
Charles Carter)
)
and)

Kwame Stringfield

and

Jeralyn Rittenhouse

and

Bikram K. Pradhan

and

James A. Weaver

and

Susann Kellogg

and

Brent Weaver

and

Dzung Hoang

and

Ricardo Melendez

and

Ed Dolly

and

Eugene Gabriyelov

and

Renee McCoy

Defendants,

COMES NOW, Plaintiffs, by and through their Attorney, Christopher M. Young, and for their Complaint in this action both individually and as a whole against Defendants: and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action to recover damages and civil penalties on behalf of the United States under the Federal False Claim Act 31 U.S.C. §§ 3729-33 against the Centers for Medicare & Medicaid Services (CMS) and the North Carolina Department of Health and Human Services (NCDHHS). These entities are collectively referred to hereinafter as Defendants.
2. This case is about CMS wasteful funding, and NCDHHS wasteful spending.
3. CMS is the federal agency that provides health coverage to more than 160 million through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS works in partnership with the entire healthcare community to

improve quality, equity, and outcomes in the healthcare system.

4. NCDHHS manages the delivery of health and human-related services for all North Carolinians, especially our most vulnerable people-children, elderly, disabled and low-income families. The Department works closely with healthcare professionals, community leaders, advocacy groups, local, state, and federal entities, as well as many other stakeholders, to make this happen.

JURISDICTION AND VENUE

5. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

6. No public disclosures of the allegations or transactions contained herein bar jurisdiction under 31 U.S.C. § 3730(e).

PARTIES

7. Relator William R. Morehead is a United States citizen and a resident of Wake County, located in North Carolina.

8. Relator Rhonda Keyes-Morehead is a United States citizen and a resident of Wake County, located in North Carolina.

9. Defendant DHHS is headquartered in Raleigh, N.C., and provides services with offices throughout the entire state of N.C.

10. Defendant Kody Kinsley sued in his official capacity as the Secretary of the North Carolina Department of Health and Human Services.

11. Defendant CMS is headquartered in Baltimore, Maryland, with regional offices throughout the United States of America namely in: Boston, Mass., New York, NY., Philadelphia, Pa., Atlanta, Ga., Chicago, Ill., Dallas, Tx., Kansas City, Mo., Denver, Co., San Francisco, Ca., and Seattle, WA.

12. Defendant Chiquita Brooks-LaSure, sued in her official capacity, is the Administrator of the Centers for Medicare and Medicaid Services

13. Defendant Dr. Mandy Cohen is the former Secretary of the North Carolina Department of Health and Human Services.

14. Defendant Dr. Cardra E. Burns is the Chief Transformation Officer and was previously Deputy Secretary for Operational Excellence for NCDHHS.

15. Defendant Dave Richard is the former Deputy Secretary of NC

Medicaid, Division of Health Benefits DHB for NCHHS.

16. Defendant Jay Ludlam is a Deputy Secretary of NC Medicaid and was previously Assistant Secretary of NC Medicaid, DHB for NCDHHS.

17. Defendant Melanie Bush is Deputy Director of NC Medicaid and was previously Chief Operating Officer of Medicaid, and prior to that, Deputy Director for Benefits and Services of NC Medicaid, DHB for NCDHHS.

18. Defendant Sandra Terrell is Chief Clinical Officer of Medicaid, previously Director of Benefits & Services for NC Medicaid, DHB for NCDHHS.

19. Defendant Sam Gibbs is a former Deputy Secretary for Technology and Operations, ITD for NCDHHS.

20. Defendant Steve Tedder is the Chief Information Officer and previously Deputy Chief Information Officer, ITD for NCDHHS.

21. Defendant Charles Carter was the Assistant Secretary for Technology Services, previously Chief Operating Officer, ITD for NCDHHS.

22. Defendant Kwame Stringfield was the Program Director for

Medicaid Enterprise Systems (MES) and IT Project Manager II, ITD for NCDHHS.

23. Defendant Jeralyn Rittenhouse was the Deputy Program Manager for MES and IT QA Manager, ITD (former) for NCDHHS.

24. Defendant Vijay Ramanujam, Director of NC FAST, ITD for NCDHHS.

25. Defendant Bikram K. Pradhan, formerly the System Integration Engineer for the MES Program, ITD for NCDHHS.

26. Defendant James A. Weaver is Secretary and State Chief Information Officer for the NC Department of Information Technology.

27. Defendant Susan Kellogg was the former Chief Deputy State CIO for the NC Department of Information Technology.

28. Defendant Brent Weaver is the Director of Data and System Group (DSG), Center for Medicaid and Children's Health Insurance Program (CHIP) for CMS.

29. Defendant Dzung Hoang is the Director of the Division of HITECH and Medicaid Management Information Systems (MMIS), DSG, Center for Medicaid and Children's Health Insurance Program

(CHIP) for CMS.

30. Defendant Ricardo Melendez is Deputy Director of HITECH and MMIS, DSG Center for Medicaid, and CHIP for CMS, and was formerly the Medicaid Enterprise Systems (MES) State Officer for North Carolina.

31. Defendant Ed Dolly is the Director of the Division of State Systems, DSG, Center for Medicaid and CHIP for CMS.

32. Defendant Eugene Gabriyelov is a Deputy Director for the Division of State Systems, DSG, Center for Medicaid and CHIP for CMS.

BRIEF OVERVIEW OF ALLEGATIONS

33. For the period between February 1, 2018, and November 19, 2021, and beyond, NC DHHS falsified documents to the Centers for Medicare and Medicaid Services (CMS) to obtain Federal Funding Participation (FFP) and program and project approvals.

34. For the period between February 1, 2018, and November 19, 2021, and beyond, the North Carolina Department of Health and Human Services (NC DHHS) did not use FFP dollars for the purposes presented to CMS.

35. Between February 1, 2018, and November 19, 2021, and beyond, CMS, without evidence to support the level of the monetary requests, provided the State of North Carolina with maximum FFP.

36. Since June 30, 2018, NC DHHS has excessively used non-competitive bidding processes to award multiple Medicaid systems and technology contracts.

37. Since June 30, 2018, CMS has approved NC DHHS contracts for Medicaid systems beyond their contract extension periods without receiving clear plans from NC DHHS for replacing Medicaid systems and technology.

38. Between February 1, 2018 and November 19, 2021 and beyond, NC DHHS has not complied with Federal Rules and Regulations, including the Patient Protection and Affordable Care Act (PPACA), the Patient Access and Interoperability final rule, the Health Information Technology for Economic and Clinical Health (HITECH) Act, the Medicaid Information Technology Architecture (MITA), and numerous Code of Federal Regulations related to the use of FFP and the implementation of information systems that support the State's Medicaid Program.

39. Between February 1, 2018, and November 19, 2021, and beyond, CMS approved projects and programs for NC Medicaid systems despite clear evidence that NC DHHS did not comply with Federal rules and regulations and, in so doing, harmed North Carolinians.

APPLICABLE LAW

40. Medicaid was originally enacted in 1965, and it required states to cover only "certain discrete categories of needy individuals- pregnant women, children, needy families, the blind, the elderly, and the disabled." National Federation of Independent Business v. Sebelius, 567 U.S. 519, 575 (2012); see also 42 U.S.C. § 1396a et seq.; see also Alexander v. Choate, 469 U.S. 287, 289 n.1 (1985) (noting that Congress designed Medicaid to "subsidize[ ]" States in "funding…medical services for the needy").

41. Medicaid is the quintessential "cooperative federalism" program. King v. Smith, 392 U.S. 309, 316 (1968). It is "financed largely by the federal government" but administered by the States" Id.

42. The Social Security Act charges the Secretary of Health and Human Services with a wide range of administrative responsibilities relating to maintaining the programs under HHS's purview,

including Medicaid. See 42 U.S.C. § 301 et seq.

43. States that elect to participate in Medicaid must propose comprehensive State plans that meet federal requirements. See 42 U.S.C. § 1396a; 42 C.F.R. §§430.10-25. "Once each plan is approved, the States 'administer Medicaid with little to no oversight, but the federal government pays a large portion of state administrative expenses.'" Texas v. Brooks-LaSure, 2021 WL 5154219, at 1 (E.D. Tex. Aug. 20, 2021).

44. The Centers for Medicare & Medicaid Services (CMS) has primary responsibility for overseeing the Medicare and Medicaid programs.

45. "To [ensure] that Medicaid's general requirements do not stand in the way of useful innovation in low income healthcare coverage, section 1115 of the Social Security Act allows states, with the permission of the federal government, to experiment with innovative approaches to Medicaid administration. 1962 U.S.C.C.A.N. 1943,1961. To this end, Section 1115 allows States and the federal government to work collaboratively to implement innovative Medicaid programs. Although Medicaid establishes certain minimum requirements, Section 1115 allows states to deviate from them in the

form of "experimental, pilot. Or demonstration projects[s]." 42 U.S.C. §1315(a). Section 1115 authorizes the Secretary to approve "any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives "of Medicaid. Id. The Social Security Act authorizes the Secretary of HHS to approve these projects. 42 U.S.C. § 1315(a). The Secretary has largely delegated this authority to CMS' Administrator. 42 CFR§ 430.25(f)(2).

46. The False Claims Act (FCA) outlines various types of conduct that can result in liability, including but not limited to as outlined in 31 U.S.C. § 3729(a)(1): presenting false claims, making false records, conspiring to commit violations, reversing false claims, possessing money of the U.S., and using false records.

STATEMENT OF RELATORS' DIRECT AND INDEPENDENT KNOWLEDGE

47. Relator William R. Morehead was employed with NC DHHS as a Project Manager for Independent Verification and Validation from February 1, 2018, until January 31, 2020.

48. Mr. Morehead was a consultant to the NC Department of

Information Technology (DIT) as an Information Technology Quality Assurance Manager from February 1, 2020, until November 30, 2020.

49. Mr. Morehead was a temporary State employee with the NC Department of Information Technology (DIT) as an IV&V Project Manager and CMS Liaison from December 1, 2020, until October 29, 2021.

50. Relator Rhonda M. Keyes-Morehead was a consultant to NC DHHS from December 1, 2020, until November 19, 2021. She started as a Product Manager and separated as a Systems Modernization Specialist.

51. Through their employment, the Plaintiffs gained access to original information in the form of witnessed meetings, email correspondence, Advanced Planning Document Updates (APDUs), budgets, project plans, Requests for Additional Information (RAIs), responses to RAIs, organization charts, Concepts of Operations (CONOPs), contracts, State Self-assessments, systems documentation, and other items that support their allegations.

52. Through their employment, the Plaintiffs found that NC DHHS

submitted false claims to the government to receive FFP and approvals for procurements and program and project resources.

53. Through his employment, Mr. Morehead found evidence of NC DHHS using false financial records and statements that were material to requests for FFP made to CMS.

54. Through her employment, Ms. Keyes-Morehead found evidence that NC DHHS did not implement the business processes modeled by the Medicaid Information Technology Architecture (MITA) despite requests for maximum FFP.

55. Through her employment, Ms. Keyes-Morehead found evidence that NC DHHS was not planning to seamlessly connect to the Health Information Exchange (HIE) and Health Insurance Exchange (HIX) despite requests for maximum FFP.

56. Through their employment, the Plaintiffs found evidence of a conspiracy among NC DHHS State employees to make fraudulent claims and receive FFP.

57. Through their employment, the Plaintiffs found evidence of a conspiracy among CMS employees to accept fraudulent claims from and pay money to NC DHHS.

58. Through his employment, Mr. Morehead found evidence that NC DHHS had knowingly concealed its obligation to return unused FFP to CMS.

FALSE CLAIMS

59. The following individuals, Kwame Stringfield, Jay Ludlam, Melanie Bush, Dave Richard, Kody Kinsley, Dr. Cardra E. Burns. Mandy Cohen, Sandra Terrell, Sam Gibbs, Steve Tedder, Charles Carter, Jeralyn Rittenhouse, Bikram K. Pradhan, James Weaver, and Susan Kellog knowingly presented or caused to be presented falsified documents to the Centers for Medicare and Medicaid Services (CMS) in an attempt to secure Federal Funding Participation (FFP) and program and project approvals.

60. On or about June 26, 2020, the State of North Carolina submitted a document entitled NC Medicaid Integrated Modular Solution (NCMIMS) Concept of Operations (ConOps), Version 1.0, to CMS.

61. The document falsely stated that "The purpose of this project is to replace the current MMIS with a modern Medicaid Enterprise System (MES) while advancing the Medicaid Information Technology Architecture (MITA) maturity levels of our business processes in support of the NC DHHS business goals, objectives, and priorities."

62. The State completed a State Self-Assessment (SSA) two years before it submitted the ConOps v.1.0. Output of the SSA included As-is and To-be Process documents, which Jay Ludlam signed on or about June 2018. The To-be Process documents were blueprints for implementation staff working to deliver the new future MES. However, it was discovered that the To-be Process documents, in contradiction to the State's claims, actually illustrated the continued use of the existing MMIS and system for reporting and analytics (i.e., NCTracks and NCAnalytics), thereby revealing a clear intent to mislead.

63. Representatives from the NC DHHS alleged: "While there may be some enhancements needed to the current MMIS systems to support the transition to MES, the Department is making every effort to minimize how many changes are made to those systems.

64. However, during that time, contracts for the existing NCTracks and NCAnalytics were repeatedly extended with no detailed project plan for modernization.

65. Representatives from the NC DHHS also alleged "The Department is committed to continuously improve the NC DHHS systems and process in order to realize additional business value and advance the NC DHHS MITA Maturity Levels."

66. Internal discussions and the State Medicaid Health Information Technology Plans (SMHPs) year after year cite Level 3 as the State's goal for MITA Maturity.

67. A later ConOps v.2.0, submitted to CMS on or about July 30, 2021, stated, "Consistent with the goals outlined in the most recent submission of the MITA State Self-Assessment (SS-A), North Carolina Medicaid's new environment will consist of technology and processes that will bring the capabilities to a level three (3) or higher in all areas of the business, information, and technical architectures."

68. NC's Capability Maturity goals have not been updated to the effective dates of Federal rules and regulations, and there were no plans to do so.

69. The State knew the Interoperability and Patient Access final rule called for widespread and secure access to clinical data in 2021, a functionality introduced at MITA Maturity Model (MMM) Level 4. However, it sustained the position it would deliver a future system with Level 3 maturity.

70. NC was not committed to continuously improving NC DHHS systems and processes; the State did not follow the MITA framework and initiative beyond using the MITA naming convention for some modules and processes.

71. NC ignored the business, information, and technical architecture domains in the planning and design stage.

72. NC presented presentations to CMS during MES Unified Monthly Status Meetings, which consistently showed MES Program Project Major Milestones, accomplishments, and activities lining up with MMIS rather than MES modules and functionality.

73. The State used an automated third-party tool named MITA Pulse.

74. NC Medicaid business and technical staff entered capability information into the automated tool, which assessed the condition of existing systems and technology and enabled planning for the future.

75. Year over year, the State did not do any of the work necessary to achieve a Maturity Level higher than Level 3. Such work would have involved the development of Conceptual and Logical Data Models, adopting information and technology standards, and plans to seamlessly connect Medicaid systems to the Health Information Exchange (HIE) and Health Insurance Exchange (HIX).

76. The state of NC also alleged: "While there may be some enhancements needed to the current MMIS systems to support the transition to MES, the Department is making every effort to minimize how many changes are made to those systems."

77. Contracts for the existing NCTracks and NCAnalytics were repeatedly extended with no detailed project plan for modernization.

78. Vendors for NCTracks and NCAnalytics implemented major system changes, including functionality to enable a shift from fee-for-service to managed care.

79. On or about May 4, 2021, Kwame Stringfield, Sandra Terrell, and others participated in a Microsoft Teams Meeting to discuss implementing the PBM Module before NCAnalytics was replaced.

80. Specifically, on the table was how to modify NCAnalytics to accommodate a real-time transaction standard for electronic formats related to the National Council for Prescription Drug Program - NCPDP). Stringfield and Terrell advocated changes to NCAnalytics despite the NCAnalytics vendor estimating an increased cost and extended schedule to modify the outmoded system.

81. One method considered was designing new Pharmacy tables in NCAnalytics. The estimated cost was $3M, and the implementation time was 25 months. Another consideration was to have parallel overlapping systems, which would result in the State paying twice for the same functionality.

82. There were never any plans to decommission the older systems and smoothly transition to a new one. However, project plans and status reports did not show activities for crosswalking functionality from the older systems to the new ones.

83. On July 20, 2021, Don Rowe, the IT Vendor Performance Manager for MES, communicated that decommissioning NCTracks was not covered under the existing contract or APD for NCTracks.

84. The MES Program communicated in status meetings on or about November 18, 2021, that it was waiting to receive decommissioning cost and time estimates from the vendors for NCTracks and NCAnalytics.

85. NC had already extended both contracts beyond their 2020 end dates to 2024. Without clear plans for replacing NCTracks and NCAnalytics and little to no incentive for the incumbent vendors to cooperate, the State was in the position to extend the contracts again.

86. NC DHHS also alleged: "The approach to implementing the NCMIMS is to purchase individual modules that align with the MITA 3.0 framework and meet State and CMS requirements. These procurements will include the technology, implementation services, and operational services (technical and clinical)."

87. MITA does not model the modules NCDHHS has moved forward to procure, including the Pharmacy Benefit Manager (PBM) module

and the National Association of State Procurement Officials (NASPO) version of the Provider Management module, which includes functionality for provider enrollment.

88. NC DHHS alleged: "Key design goals for the NCMIMS have been established to ensure that all business and technological objectives are met and to fully align with MITA 3.0 and the CMS Seven Standards and Conditions."

89. NC DHHS did not follow the Business, Information, or Technical Architecture modeled by MITA 3.0 to ensure alignment. The State developed and worked on a tailored approach that CMS did not preapprove.

90. NC had no straightforward design or blueprint for its tailored approach.

91. NC DHHS alleged: "To achieve the MITA Maturity Level 4 or 5, the NCMIMS is moving towards the cloud first strategy."

92. NC DHHS had not adopted the MITA business-aligned processes at publication or even documented its tailored-to-be business processes in a manner that would enable cloud services.

93. On or about July 30, 2021, Kwame Stringfield, Jay Ludlam, and Dave Richard submitted a document entitled NC Medicaid Integrated Modular Solution (NCMIMS) Concept of Operations (ConOps), Version: 2.0.

94. The document made the following false claims: "The NC MIMS system will be characterized by the integration of modularized SaaS and COTS solutions, which are highly decoupled, connected through a service-oriented software solution that will be rules based, and will provide alignment with the MITA 3.0 Framework," and "The MES Program will satisfy the CMS Seven (7) Standards and Conditions," and lastly "The NC MIMS implementation approach is to acquire or build individual solutions that support the new modules that align with the MITA 3.0 framework and meet state and CMS requirements."

95. Those statements were false because NC DHHS planned and procured modules that merged and duplicated business processes across modules, including a Pharmacy Benefit Manager (PBM) solution that duplicated processes in Care Management, Financial Management, Operations Management, Member Management, Plan

Management, and Performance Management. Another example is NC's merging business processes for provider, eligibility, and enrollment management. Duplicating processes and merging modules are openly at variance with MITA and the concept of being "highly decoupled."

96. CMS required NC to separate its business rules from core programming and ensure they would be in human and machine-readable formats. Stating that the system would be "rules-based" implied that this modularity standard would be met. However, NC did not document the business rules (only system requirements) and planned and procured modules based on solutions that included proprietary business rules that could not be separated to meet the Modularity Standard.

97. On or about July 30, 2021, North Carolina submitted a request for CMS to review and approve the State's Advance Planning Document Update (APD-U) for its system named North Carolina Families Accessing Services through Technology (NC FAST).

98. The NC FAST 2021 Annual APD-U was submitted as an effort managed by a collection of divisions, also known as a Multiple

Operations Division (Multi-Ops Div), to the following federal partners that provide funding for these efforts: the US DHHS Administration for Children and Families (ACF), US DHHS Centers for Medicare and Medicaid Services (CMS) and US Department of Agriculture, Food and Nutrition Service (FNS).

99. NC's APD-U contained several line items that the assigned State Officer (SO) questioned.

100. After multiple rounds of Requests for Additional Information (RAIs) and related responses, CMS issued an RAI on or about September 22, 2021, and the State responded on or about October 11, 2021. Through information and belief, the Relators believe the CMS State Officer analyzed several items of concern and documented them in a Decision Paper. The Relators believe the Decision Paper escalated within CMS on or about December 7, 2021.

101. Through information and belief, the Relators believe CMS met with NC on or about December 9, 2021, to discuss and issue the approved recommendations outlined in the Decision Paper. The Relators believe that during the meeting, CMS notified the State that NC would receive partial approval of FFP funding for State and

Contractor Costs, with an expiration date of March 31, 2022. This would allow CMS and the State sufficient time to properly analyze the data they had provided to understand the cost elements of the State's request. The Relators believe the State was given until February 1, 2022, to develop and communicate a path forward for analyzing the data and that CMS indicated it would review the proposed approach for data analysis and either concur or request a different approach.

102. Through information and belief, the Relators believe on or about January 31, 2022, NC submitted a new APD-U requesting an extension to provide FFP for funding State and Contractor Costs to allow additional time to validate the previously provided data to CMS. The request was to extend the date from March 31, 2022, to May 31, 2022. This submission also included the asked-for approach on how the State would validate the data results by selecting five (5) of the State's largest counties out of one hundred (100) counties to run its analytics.

103. Through information and belief, the Relators believe that on or about March 3, 2022, CMS approved the extension of the partial FFP

until about September 30, 2022, and asked the State to perform the analysis using a recommended CMS approach. The State would then submit their results to CMS for full review and approval of the requested funding. In the end, however, the State submitted information inconsistent with the original CMS request. CMS submitted the findings to its Financial Management Group (FMG) for a Financial Management Review.

MISUSE OF FEDERAL FUNDING PARTICIPATION (FFP)

104. The following individuals, Dave Richard, Jay Ludlam, Melanie Bush, Sandra Terrell, Sam Gibbs, Charles Carter, Steve Tedder, and Kwame Stringfield, knowingly used or caused to be used Federal Funding Participation (FFP) dollars for purposes other than those presented to the Federal Government.

105. NC combined FFP intended for the design, development, and implementation of Medicaid Enterprise Systems (MES) with funds for modifying NCTracks and NCAnalytics, transforming the NC Medicaid Program from a fee-for-service model to a managed care model, implementing an Electronic Visit Verification (EVV) system, and procuring modules for Pharmacy Benefits Management (PBM) and

Provider Management. The latter two modules were based on defunct Medicaid Management Information System (MMIS) requirements, creating a complex web of fund usage.

106. From September 22, 2021, and beyond, communications between CMS, the NC Office of the State Auditor, and the NC Department of Health and Human Services (NC DHHS) reveal the significant adverse effects of this misuse of FFP.

107. On or about September 15, 2020, the State of North Carolina submitted a Planning Advance Planning Document Update (PAPD-U): MES Program, NC MIMS Replacement Project (P-APDU #20170228P-04) document. The title itself implied the PAPD-U was requesting resources for a replacement effort. However, as an example of the issues, the body of the document read: "Since approval of the base PAPD for the Medicaid Enterprise System (MES) Program Management Office (PMO) and the subsequent update, it was determined that the state-legislated switch to Managed Care requires DHHS to first conduct a modernization exercise to update the existing MMIS and Analytics platforms to accommodate the IT system needs of NC's Medicaid Reform (Session Law 2015-275 [HB 372]) directive

to perform the Medicaid Program Transformation exercise to the managed care model. This modernization is a direct result of 1115 waiver activities (Session Law 2016-121 [SB 838]) driving the future IT system requirements to support the Medicaid Reform and overall transformation of the program. The timeline for implementing the approved CMS 1115 Waiver changed from Feb 1, 2020 to the current July 1, 2021 which necessitated corresponding changes to MES activities. These changes however will not impact the final objective of a new MIMS implementation target completion date of June 30, 2024."

108. Before and beyond 2020, MES Program staff entered time for work into an NC DHHS IT Time Tracking system using a single project billing code. In addition, multiple contractors entered time into Vector, a State of NC time tracking system using a single project billing code. The hours pooled included work performed on MES, NCTracks, NCAnalytics, Managed Care Transformation, EVV, PBM, and tailored processes and modules not approved by CMS. As a result, the State failed to record and account for work on MES properly during that period.

109. CMS approved FFP at the 90% rate to implement MITA business-aligned processes and modules, in keeping with its Twenty-two Standards and Conditions and terms laid out in its letter to State Medicaid Directors, SMD # 18-005 RE: CMS-2392-F Mechanized Claims Processing and Information Retrieval Systems –Reuse. However, the enhanced FFP was used to plan and procure tailored modules instead of the MITA business-aligned modules.

110. The State directed MES Program personnel to work on tailored and duplicated functionality under the auspice of having CMS approval. CMS-approved FFP to enable seamless connections between NC \MIMS and the Health Information Exchange (HIE). However, that FFP was instead used to plan how to duplicate HIE data into a new data warehouse.

111. On or about January 19, 2021, NC and CMS started a series of communications related to an HIE Implementation Advanced Planning Document (IAPD). CMS Requests for Additional Information (RAI) and responses from NC illustrate the State's intent to "ingest and analyze" HIE data using NCAnalytics.

112. In a series of communications beginning on or about May 11, 2021, between herself, the Business Integration Architect, and the MES Enterprise Architect, Ms. Keyes-Morehead sought to clarify whether NC Medicaid intended to connect to the HIE seamlessly. The architects described plans to duplicate HIE data in a new decision support system and data warehouse and suggested CMS had reviewed and approved the effort.

113. In a series of communications beginning on or about May 17, 2021, between herself, the DHB|MES Relationship Manager, and Kwame Stringfield, Ms. Keyes-Morehead sought to clarify whether the new MES would eventually replace a then-newly delivered Encounter Processing System (EPS) that relied on NC Tracks reference data extracts and EDI. The response was that the EPS delivered in 2021 would be the EPS ongoing. This is despite the shift from EDI to API and the CMS model to include a process for encounters in the Operations Management module.

CMS ACTED WITHOUT EVIDENCE

114. The Code of Federal Regulations (CFR) Title 42 Section 433.112 outlines standards and conditions to receive Federal Funding

Participation (FFP) for designing, developing, installing, or enhancing Medicaid's mechanized processing and information retrieval systems. The following key individuals, Chiquita Brooks-LaSure, Brent Weaver, Dzung Hoang, Ricardo Melendez, Ed Dolly, and Eugene Gabriyelov, who were in positions of authority and responsibility, knowingly made available or caused to be made available Federal Funding Participation (FFP) dollars to the State of North Carolina without concrete evidence the State met the standards and conditions specified in 42 CFR Section 433.112.

115. Between June 26, 2020, and April 14, 2022, CMS provided enhanced funding to NC Medicaid without having an approved Medicaid Management Information System (MMIS) Concept of Operations (COO), which was required at the time as per the Medicaid Enterprise Certification Lifecycle (MECL).

116. On or about April 14, 2022, CMS published a letter to State Medicaid Directors, SMD # 22-001, RE: Updated Medicaid Information Technology Systems Guidance: Streamlined, Modular Certification for Medicaid Enterprise Systems. The letter introduced a certification process for modules. It immediately ended the processes

published in the Medicaid Enterprise Certification Toolkit (MECT) and the Medicaid Eligibility and Enrollment Toolkit (MEET). This direction was long-awaited, as it was well-known that the MECT, which IT professionals used to build the MMIS, omitted requirements for twenty-two of the eighty business processes required to build Medicaid Enterprise Systems (MES) as prescribed by the Medicaid Information Technology Architecture (MITA). In other words, MES could not be built using the outdated toolkit that was explicitly designed to build an MMIS.

117. On or about November 6, 2023, CMS approved a contract that NC awarded to Magellan Medicaid Administration LLC for implementing a Pharmacy Benefits Manager Module (PBM). The PBM is not an MES module, and it bifurcates claims processing in a manner that does not support transparency. It also duplicates processes across Medicaid eligibility and enrollment, financial, operations, plan, and performance management. The State's request to procure a PBM made it apparent NC did not have an "aggressive decoupling strategy," as CMS guided states to have in its publication titled Enhanced Funding Requirements: Seven Conditions and Standards Medicaid IT

Supplement (MITS-11-01-v1.0), which was released years prior in April 2011.

118. CMS also funded work on procuring the MMIS version of the Provider Management Module, which coupled business processes for provider enrollment. In the MES environment, the provider enrollment process is in an entirely separate module designed explicitly for managing eligibility and enrollment.

119. CMS repeatedly granted FFP to NC despite the State's poor delivery record and imprecise requests for funding that were unclear, lacked necessary details, and were inconsistent with the CMS model for health information technology.

120. CMS authorized enhanced FFP for NC's MMIS Replacement Project starting on or about February 28, 2017. Several years later, NC had not delivered a single MES MITA business-aligned module. Yet, CMS was still authorizing enhanced FFP.

121. On or about October 2, 2020, NC procured an Electronic Visit Verification (EVV) system from Sandata Technologies using FFP. EVV systems are used for personal care and home health services that involve in-home provider visits. Using EVV systems, caregivers log

specific in and out times along with their location to ensure patients receive authorized services. EVV systems then submit claims directly to Medicaid. The goal of EVV systems is to reduce fraud, waste, and abuse while ensuring accurate billing of Medicaid. Seamless integration and compatibility are crucial to avoiding technical difficulties. However, NCTracks is not cloud native. That is to say, it is not based on modern applications or cloud services, it is not broken down into smaller parts that handle specific functions (i.e., microservices), and it does not allow for seamless integration and compatibility with modern mobile devices or other modern applications. As a result, NC's EVV implementation was fraught with problems and did not meet expectations. On or about March 12, 2024, Jay Ludlam announced to the NC Joint Legislative Oversight Committee on Medicaid a plan to "roll back EVV for Home Health."

122. On or about January 2021, CMS approved a contract that NC awarded to KPMG for systems integration. CMS did so without NC's baselined project plans for decommissioning the existing NCTracks and designs for delivering modern MES modules. In other words, CMS approved middleware for integrating systems without having a clear

picture of what systems the State planned to integrate and when. NC ended its contract with the systems integration platform (SIP) provider in early 2024.

EXCESSIVE USE OF NON-COMPETITIVE BIDDING

123. The following key individuals, including Kody H. Kinsley, Mandy Cohen, Dr. Cardra E. Burns, Dave Richard, Jay Ludlam, Melanie Bush, Sandra Terrell, Sam Gibbs, Steve Tedder, Charles Carter, Kwame Stringfield, Jeralyn Rittenhouse, Bikram K Pradhan, excessively used or caused to be used non-competitive bidding processes to award multiple contracts for Medicaid systems, technology and related services.

124. The State of North Carolina extended several contracts more than once on a sole-source basis, significantly impacting the competitive landscape and the potential for fair and open bidding. In 2008, N.C. awarded CSC its Medicaid Management Information System (MMIS) contract. CSC implemented the MMIS, NCTracks, in 2013.

125. The contract's end date was June 30, 2018, but it included two optional years that allowed it to extend until June 29, 2020. (In 2018, CSC/CSRA became GDIT).

126. In June 2024, the contract was sole sourced for the fourth additional year beyond its initial contract.

127. Truven/IBM has been contracted with the state of North Carolina to deliver Reporting & Analytics for fourteen years.

128. In 2011, North Carolina progressively awarded Accenture a contract to integrate the North Carolina Families Accessing Services through Technology (NC FAST) system. The original end date for the contract was June 31, 2016, but the contract followed a progressive award strategy, and Accenture was awarded multiple subsequent projects. In 2015, through its fifth amendment, NC authorized a 3-year contract extension plus two optional 1-year extensions for operations and maintenance support. After ten contract amendments, the contract end date was August 30, 2020.

129. In 2018, NC authorized Accenture to establish a Program Management Office responsible for Medicaid Transformation and delivery of the To-be Processes for Medicaid Enterprise Systems (MES). The ties between this level of work and Accenture's initial role on NCFAST were questionable. In 2024, the contract was sole sourced for the fourth additional year beyond its tenth contract amendment.

Accenture has been contracted with the state of North Carolina to deliver services for thirteen years.

130. Follow-on contracts that would have replaced NCTracks, NCAnalytics, and the services Accenture provided were delayed by circumstances that were reasonably foreseeable when the initial agreements were entered into.

131. CMS finalized new rules for State Medicaid Systems in 2011, two years before GDIT implemented NCTracks and IBM implemented NCAnalytics.

132. CMS rules were based on cultural, technological, and legislative transformations that radically changed the external behavior of the systems supporting state Medicaid programs, including the ePass component of NC FAST, which processes eligibility.

133. CMS published numerous documents to notify and train states to understand the cultural, technological, and legislative changes necessitating a shift from MMIS to MES and guide states' planning efforts.

134. The State of North Carolina created the circumstances that prevented transitioning to the CMS model and forced the contract extensions.

135. Despite receiving training, guidance, and ample funding from CMS, North Carolina directed its efforts to deliver an MMIS instead of an MES. Consequently, the State met resistance from external partners, beneficiaries, and vendors who were rightly following the CMS model. Many of the State's efforts stalled because NC's actions were not in line with the National Quality Strategy and the National Health Information Technology (HIT) infrastructure, which allows for the electronic use and exchange of information.

136. During their employment, Ms. Keyes-Morehead and Mr. Morehead delivered a series of emails, presentations, working papers, and other communications that cited Federal rules and regulations, State Medicaid Director (SMD) Letters, the Medicaid Information Technology Architecture (MITA), advice from the State's legal advisors, and other resources to persuade the State to follow the Federal model for modularity, connect Medicaid to the Health Information Exchange (HIE) and the Health Insurance Exchange

(HIX), and use Concepts of Operations, roadmaps, and the MITA Maturity Model to communicate intent and expectations.

137. Beginning January 1, 2021, payers were required to implement the Patient Access API and a process for payer-to-payer data exchange. However, because the legacy systems were not cloud-native, NCTracks and NCAnalytics could not enable compliance with the final rule. That meant that without replacement systems, the state was out of compliance by the compliance date.

138. State personnel were unfamiliar with the State's HIE and the Federally Facilitated HIX ("the Exchanges"). In addition, state personnel did not understand the importance of data standards to interoperability and insisted that the System Integration Platform (SIP) alone would ensure interoperability.

139. The State worked ahead of CMS approvals for Implementation Advanced Planning Document (IAPD), MITA Concept of Operations (ConOps), and MMIS Concept of Operations (ConOps).

140. It has remained unclear who ensured that MES Program methods and products met Federal rules and regulations and precisely who was

responsible for interrogating, interpreting, and translating Medicaid Program and Health Information Technology law.

141. It appeared North Carolina was creating a "shadow eligibility system" rather than using the federally operated Health Insurance Exchange (HIX). No scenario enabled MMIS modules to meet current federal requirements; however, NC proceeded with MMIS modules.

142. There was not any scenario that would enable both the implementation of MMIS modules and receiving enhanced FFP at the 90% rate, yet NC was implementing MMIS modules and receiving the 90% FFP rate; there was no Data Management Strategy (DMS).

CMS ALLOWED NON-COMPLIANCE

143. The following key individuals played a significant role in allowing or enabling the State of North Carolina to improperly avoid its obligation to comply with Federal rules and regulations: Chiquita Brooks-LaSure, Brent Weaver, Dzung Hoang, Ricardo Melendez, Ed Dolly, and Eugene Gabriyelov. Their actions raised serious concerns about accountability and transparency in Medicaid administration.

144. On or about February 28, 2017, CMS approved NC's project to replace its Medicaid Management Information System (MMIS).

Astonishingly, through and beyond November 2021, CMS approved enhanced Federal Funding Participation (FFP) for NC without receiving clear, detailed, and baselined project plans for replacing Medicaid systems and technology. The plans missing or lacking information were those for cash flows, personnel resources, and deliverables.

145. Between February 2017 and November 2021 and beyond, NC did not deliver a single Medicaid Enterprise Systems (MES) module. Yet, despite its poor performance, the State still obtained 90% FFP from CMS.

146. CMS did not adhere to its own guidance, rules, and regulations for approving MMIS replacement projects and funding, which was a significant departure from expectations.

147. In September 2020, the U.S. Government Accounting Office (GAO) released a substantial report titled "Medicaid Information Technology: Effective CMS Oversight and States' Sharing of Claims Processing and Information Retrieval Systems Can Reduce Costs."

148. Between 2020 and 2024, the State requested CMS approval to extend contracts for existing systems. Since there were no

replacement systems, CMS obliged. This continuous extension of contracts indicates the impact the lack of planning had on MMIS replacement in the State.

149. In its September 2020 report, the GAO recommended that CMS actively encourage states to share IT systems to reduce duplication. Adopting the CMS model for Medicaid Enterprise Systems (MES) was critical to sharing because it guided states to adopt uniform processes, which in turn prevented the customization that made sharing solutions difficult.

150. Based on information and belief, the Relators believe that on or about July 2022, NC submitted a Planning Advance Planning Document (PAPD-U) for the NC MIMS Replacement Project. The document requested approval for a mixture of MMIS- and MES-based projects and procurements. All of the requested funding was at the enhanced 90% FFP rate.

151. The PAPD-U listed the State's plans to procure a Provider Data Management/Credential Verification Organization (CVO) to manage and maintain the Provider Information, Enrollment, Credentialing, and Business operations details. The document stated this was a

NASPO product and included enrollment processes. The inclusion of enrollment processes made it evident that the provider data management module the state planned was based on the outdated MMIS approach because enrollment in the MES environment was included in a separate module for eligibility and enrollment.

152. The mixture of MMIS and MES components established the State's intent to implement a tailored approach. Although the Provider Data Management module was a NASPO product shared with other states, it was a soon-to-be-deprecated module being adopted for the State's future use. This approach would not encourage future reuse and was not in keeping with CMS' Leverage Condition.

153. On or about August 16, 2016, CMS wrote a letter to State Medicaid Directors (SMD) RE: CMS-2392-F Mechanized Claims Processing and Information Retrieval Systems – Modularity.

154. The letter stated, "CMS has organized the requirements in the MECT into checklist sets to be used in certifying MMIS modules. States can use MECT checklists based on 1) the MITA 3.0 business areas, 2) MMIS modules, or 3) a tailored checklist set prepared by the state, which the state then submits to CMS for acceptance. Appendix

A lists the MITA 3.0 and MMIS business area checklists. Whichever checklist set is used, the MITA 3.0 requirements still apply."

155. The MECT checklists for option 2, MMIS modules, were missing twenty-two MITA business processes, negating the later statement, "MITA 3.0 requirements still apply."

156. Despite requiring preapproval of "3) a tailored checklist set prepared by the state, which the state then submits to CMS for acceptance," CMS funded NC's tailored approach without NC presenting a tailored checklist set to CMS.

157. On or about April 14, 2022, CMS wrote SMD # 22-001 RE: Updated Medicaid Information Technology Systems Guidance: Streamlined Modular Certification for Medicaid Enterprise Systems.

158. Amongst other ambiguous statements, the letter introduced Table 1 Examples of MES Modules, stating, "The MES modules that support a state's Medicaid operations typically include the modules described in Table 1 and their general functions (non-exhaustive list)." However, the components listed in Table 1 did not abide by the naming convention used in MITA for modules. Table 1 does not list MITA business-aligned modules. It was untraceable to the implementation

modeled by CMS. The list of components was more closely aligned with the older MMIS components.

159. A history of Requests for Additional Information (RAIs) from CMS to the State of North Carolina revealed that CMS knew something was wrong with NC's implementation. However, CMS continued to supply enhanced FFP to NC despite receiving responses to its RAIs that did not justify noncompliance.

NORTH CAROLINA'S NON-COMPLIANCE

160. The following individuals, Kody H. Kinsley, Mandy Cohen, Dr. Cardra E. Burns, Dave Richard, Jay Ludlam, Melanie Bush, Sandra Terrell, Sam Gibbs, Steve Tedder, Charles Carter, Kwame Stringfield, Jeralyn Rittenhouse, Bikram K. Pradhan, James A. Weaver, and Susan Kellogg, did not comply or caused noncompliance with federal rules and regulations that govern the design, development, implementation and certification of information systems and technology for Medicaid services.

161. Section 1413 of the Patient Protection and Affordable Care Act (PPACA) mandates that state Medicaid programs streamline enrollment procedures through an exchange. The PPACA, which has

been in effect since January 1, 2014, aimed to simplify and make enrollment more efficient and accessible. However, between 2014 and 2021 and beyond, NC's Medicaid systems were not seamlessly connected to the Health Insurance Exchange (HIX), significantly impeding the program's enrollment efficiency and accessibility, thereby undermining the core objective of the PPACA and causing a severe impact on Medicaid services and patient access in North Carolina.

162. The 21st Century Cures Act, specifically Section 12006(a), mandates that states implement Electronic Visit Verification (EVV) for all Medicaid personal care services (PCS) and home health services (HHCS) that require an in-home visit by a provider. This is a significant requirement that state Medicaid agencies were to comply with by January 1, 2023. However, NC Medicaid did not have an EVV system functioning as intended by the deadline. On or about March 12, 2024, Jay Ludlam announced to the NC Joint Legislative Oversight Committee on Medicaid a plan to "roll back EVV for Home Health."

163. The Medicaid Information Technology Architecture (MITA) is developed from and facilitates compliance with various legislative requirements and rules, including but not limited to the Health Information Technology for Economic and Clinical Health Act (HITECH), the Children's Health Insurance Program Reauthorization Act (CHIPRA), the Patient Protection and Affordable Care Act (PPACA), and the Health Insurance Portability and Accountability Act (HIPAA). Because NC Medicaid did not follow MITA between February 2018 and November 2021 and beyond, it did not adhere to many of the legislative requirements and rules on which MITA was built.

164. HITECH, which was enacted under Title XIII of the American Recovery and Reinvestment Act (ARRA) of 2009, is a component of broader legislation promoting health information technology adoption and meaningful use in the healthcare industry. Through HITECH, providers and payers are encouraged to seamlessly connect to Health Information Exchanges (HIEs) to share and use clinical data in a way that allows for timely and quality decisions, care, and treatment.

MITA established a framework for sharing clinical data related to Medicaid beneficiaries and members.

165. All state Medicaid programs must undertake due diligence to comply with security rules under the Health Insurance Portability and Accountability Act (HIPAA). HITECH strengthened privacy and security protections for healthcare information under HIPAA. The MITA framework that allowed for the sharing of clinical data did so in a manner that lessened the risk of unauthorized disclosures by limiting duplicated data. In addition, the MITA framework enforced modularity. Enforced modularity (as opposed to soft modularity) reduces the possibility of security issues propagating from one module to an entire system.

166. The decision to not follow MITA affected the meaningful use of clinical data and the security of health information in NC's Medicaid program. These are examples of how not following MITA resulted in the State's inability to comply with legislated requirements and rules.

167. Regulations found at 42 CFR 433.111 allow CMS to grant enhanced federal funding to states meeting CMS standards and conditions and seeking more significant interaction and interoperability across the

Medicaid enterprise. Between February 2018 and November 2021 and beyond, NC received enhanced federal funding (FFP) but did not use the funds for the intended purpose or in the manner specified by the regulations. Instead, the State used the funding to plan, design, and procure modules that were tightly coupled, with many interactions between them, rather than loosely coupled modules that enforced modularity; modules that did not use or rely on clinical data to enable meaningful use; modules that did not seamlessly connect to the exchanges.

168. According to the Electronic Code of Federal Regulations Title 42, Chapter IV, Subchapter G, Part 495, Subpart D, § 495.3321, each State Medicaid Health Information Technology Plan (HIT) plan must include specific elements. These requirements ensure that state Medicaid HIT plans are comprehensive, interoperable, and aligned with current and future visions for health information technology.

169. Between 2018 and 2021 and beyond, NC's Medicaid HIT plans did not align with or clarify the alignment with Federal HIT requirements. Email communications, requests for additional information (RAIs), and responses to RAIs passed between NC and

CMS demonstrate that both parties understand the importance of the Medicaid HIT plans to CMS approvals and funding decisions.

170. The Interoperability and Patient Access Final Rule is established under the authority of the Centers for Medicare & Medicaid Services (CMS) to regulate Medicaid and other programs. This rule is part of the broader 21st Century Cures Act and supports interoperability and patient access to health information.

171. State Medicaid programs were initially to start implementing the Interoperability and Patient Access Final Rule provisions by April 1, 2022. This included the daily exchange of specific data for individuals dually eligible for Medicaid and Medicare. Additionally, Medicaid-managed care plans and CHIP-managed care entities initially had to comply with a beneficiary's request to transfer their health data from payer to payer as seamlessly as possible by January 1, 2022. Both provisions have a new compliance date of January 1, 2027.

172. Between 2018 and 2021, NC did not have comprehensive plans to comply and missed the initial compliance dates; upon information and belief the Relators believe NC Medicaid in 2024 still does not have a credible plan to meet the new compliance date.

173. This includes plans to make enrollee electronic health information held by NC Medicaid available through an API such that the information is easily accessible to enrollees and data flows seamlessly with enrollees as they change health care and social service providers and payers; it also includes plans to make it easy for current and prospective enrollees to identify which providers are within a given plan's network in a simple and easy way for enrollees to access and understand and thus find the providers that are right for them.

174. North Carolina Families Accessing Services through Technology (NC FAST) is a program NC designed to improve how its Department of Health and Human Services and county departments of social services provide services and benefits to the people of North Carolina. It is an Integrated Eligibility System (IES) designed to process eligibility and enrollment for North Carolinians applying for benefits in several federal programs, including Medicaid, Temporary Assistance for Needy Families (TANF), Child Welfare (CW), and the Supplemental Nutritional Assistance Program (SNAP), and others.

175. NC FAST was designed to use industry-leading case management software Curam to streamline the application, eligibility determination, and benefits processes.

176. Because NC FAST serves different programs, the state must submit a cost allocation plan (CAP) following 45 CFR Part 95 Subpart E.

177. CMS typically provides the largest Federal Funding Participation (FFP) rate in these submissions. One main reason is that CMS' FFP rates for system planning, design, development, and implementation (DDI) are enhanced compared to other Federal programs (typically 90% vs. 50%).

178. In addition to the CAPs contained within each project, the State must submit a Medicaid-specific CAP that is reviewed and approved by the Department of Health & Human Services (HHS) and Cost Allocation Services (CAS).

179. According to 45 CFR Part 95 Subpart E, "If a State has not submitted a plan or plan amendment during a given State fiscal year, an annual statement shall be submitted to the [Director, Division of

Cost Allocation (DCA)] certifying that its approved cost allocation plan is not outdated."

180. During Mr. Morehead's employment with the State, NC DHHS did not conform to the content requirements or submission schedule defined by 45 CFR Part 95 Subpart E. That is to say, the State failed to submit an amended cost allocation plan. Furthermore, because "A State must claim FFP for costs associated with a program only in accordance with its approved cost allocation plan.," CMS may have allowed and paid a higher FFP for NC under the State's older, previously approved CAP.

CMS PUT NORTH CAROLINIANS IN HARM'S WAY

181. The following persons, whether acting as individual regulators or as part of a collective regulatory agency, have failed in their duties and prevented North Carolinians from receiving the gains to which they are entitled under federal healthcare rules and regulations: Chiquita Brooks-LaSure, Brent Weaver, Dzung Hoang, Ricardo Melendez, Ed Dolly, and Eugene Gabriyelov.

182. The U.S. Department of Health and Human Services (US DHHS) was created as part of a Reorganization Plan authorized by the

Reorganization Act of 1949. Its primary goal is to reduce healthcare expenditures and increase efficiency, ensuring that taxpayer dollars are used responsibly.

183. The Centers for Medicare and Medicaid Services (CMS), an operating division under US DHHS, is a regulator within the healthcare system. Its operations are aligned with the broader goals and regulations established by the US DHHS, making its regulatory failure particularly severe.

184. CMS oversees and administers the nation's principal healthcare programs, including Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). It establishes and modifies regulations that impact healthcare providers, suppliers, and individuals enrolled in these programs.

185. As a regulator, CMS publishes regulations that have the force of law and affect how healthcare services are delivered and financed. It enforces compliance with the rules it sets, which may involve conducting hearings and issuing rulings. Lastly, CMS issues guidance to explain how laws will be implemented and what states and other entities must do to comply with federal healthcare policies.

186. CMS has devoted over twenty years, deployed uncountable resources, and invested a significant amount of money in directing a range of strategies designed to align and improve health outcomes, advance equity and engagement for all individuals, ensure safe and resilient healthcare systems, and accelerate interoperability and scientific innovation. These strategies include implementing significant healthcare laws like the Patient Protection and Affordable Care Act (PPACA), financing health information technology, and advancing efforts to improve healthcare quality and accessibility.

187. Since 2016, CMS has issued guidance that contradicted and failed to enforce compliance with legislation and rules affecting Medicaid information systems and technology. This failure adversely impacted the quality, accessibility, and affordability of healthcare services in North Carolina.

188. Transformation of the Nation's healthcare system, of which NC's Medicaid services are a part, has been a gradual and complex process, with legislation and rules being rolled out in series. Notable milestones include the American Recovery and Reinvestment Act (ARRA) of 2009, the Health Information Technology for Economic and

Clinical Health Act (HITECH) of 2009, and the Affordable Care Act of 2010. A Medicaid Information Technology Architecture Maturity Model (MMM) guides the progression of capabilities a state should have as it complies with the serial rollout of new Medicaid rules and regulations.

189. On or about April 14, 2022, CMS published a letter to State Medicaid Directors (SMD # 22-001) RE: Updated Medicaid Information Technology Systems Guidance: Streamlined Modular Certification (SMC) for Medicaid Enterprise Systems. The letter described a new interim certification process for modules while giving a future view of CMS' ultimate goal to move to an Outcomes-based Certification (OBC) process for Medicaid Enterprise Systems (MES).

190. 42 CFR 433.117 and 45 CFR 95.610 outline how to obtain approval for a replacement system by submitting advanced planning documents (APDs). APDs must include specific, precise information, including, for example, the schedule for when the replacement system will be in operation and a plan for the orderly transition from the system being replaced.

191. Through information and belief, the Relators believe that between February 2018 and November 2021 and beyond, the State of NC did not meet the requirements for requesting and receiving approval for enhanced funding for Medicaid Enterprise Systems (MES).

192. CMS issues guidance to states, including the methods and components for building information systems. The methods and components are typically traceable to specific rules and regulations. When replacing an old system with a new one, ensuring compliance and obtaining CMS certification largely depends on implementing the correct components. Hence, analysts carefully identify which components in the old system will be retired and which will be replaced. In addition, analysts identify which components in the new system will be introduced for the first time. CMS publishes crosswalk documents to help analysts make these determinations, ultimately facilitating a smooth cutover from old to new. The MECT and MITA are examples of CMS guidance that itemize components and include crosswalks. The MECT was in effect before passing the Patient Protection and Affordable Care Act (PPACA). MITA represents the components and crosswalks that came after the PPACA.

193. CMS certified NCTracks on or about 2013, approximately one year after the publication of MITA. This suggests that CMS certified NCTracks with the knowledge that the system met neither the requirements outlined in the MECT nor those outlined in MITA.

194. MITA transforms the systems and technologies that support Medicaid services into new Medicaid Enterprise Systems (MES). Unlike MMIS, MES includes functionality that supports eligibility and enrollment, the integration of clinical data, and seamless connections to exchanges. MES has several components.

195. Because CMS certified a system that did not match any current version, it is extremely difficult for analysts in NC to find the starting point for moving from NCTracks to the new MES. While there is a component crosswalk from MECT to MITA, there is no such crosswalk from what NCTracks is based on to MITA. Hence, CMS' allowance of NC's tailored, non-compliant approach has complicated the decommissioning of NCTracks.

196. Before approving projects and procurements and authorizing enhanced FFP, CMS historically, at a minimum, followed generally recognized good project and program management practices, such as

those put forward by the Project Management Institute (PMI) in its Project Management Body of Knowledge (PMBOK). However, CMS did not follow good project and program management practices for NC's MES Program between February 2018 and November 2021 and beyond. Instead, it enabled the MES Program to fail.

197. Because it failed to regulate NC Medicaid properly before and beyond 2018, CMS contributed to the conditions preventing low-income North Carolinians from receiving quality, affordable healthcare.

198. Based on information and belief, the Relators believe NC plans to replace NCTracks by 2028, approximately ten (10) years after CMS approved the State's MMIS Replacement Project. The Relators believe this date was announced to CMS on or about March 28, 2022, and was included in official State plans and documents.

199. Between 2018 and 2021 and beyond, NC's Medicaid HIT Plans and other submittals show the State plans to implement another Medicaid Management Information System (MMIS) instead of Medicaid Enterprise Systems (MES). This means NC will continue to lag in adopting the technology needed to improve its healthcare outcomes,

manage its expenditures, and improve performance, not just for the ten years it takes to replace NCTracks but much further into the future until the next system is replaced or retired.

200. MITA Part I Appendix A describes significant improvements the State Medicaid Agency (SMA), as well as North Carolina's beneficiaries, providers, and managed care organizations (MCOs), would have realized had CMS properly regulated NC to implement Medicaid Enterprise Systems (MES).

201. Between August 2016 and beyond, CMS enabled NC to give vendors and contractors impossible jobs, resulting in high personnel turnover.

202. NC hired vendors willing to create effective and reliable information systems that complied with Federal legislation and rules. However, because CMS failed to issue guidance and regulate NC in a manner consistent with its rules and regulations, it created confusion that resulted in high turnover among supplemental staffing and contract vendors.

203. On or about August 16, 2016, CMS issued a letter to State Medicaid Directors SMD # 16-010 RE: CMS-2392-F Mechanized Claims Processing and Information Retrieval Systems – Modularity. The

letter provided sub-regulatory guidance related to CMS-2392-F. It declared that states could "use MECT checklists based on 1) the MITA 3.0 business areas, 2) MMIS modules, or 3) a tailored checklist prepared by the state, which the state then submits to CMS for acceptance."

204. CMS' twenty-two standards and conditions, starting at 42 CFR 433.112(b)(1), include seven standards and conditions that must be met to receive enhanced federal funding for Medicaid technology investments. CMS allowed the State to implement an MMIS while at the same time insisting vendors meet its seven standards and conditions. This created a conflict. Vendors were, in effect, asked to design, develop, and implement systems that did not comply with the seven standards and conditions but somehow do so in a manner that did. This was an impossible job.

205. SMD # 16-010 stated, "CMS envisions a discrete role for the system integrator (SI) in each state, with specific focus on ensuring the integrity and interoperability of the Medicaid IT architecture and cohesiveness of the various modules incorporated into the Medicaid enterprise. The target outcome for the SI should be to foster ever

evolving solutions for Medicaid business requirements, with the SI responsible for the successful integration of the chosen solutions and infrastructure into a seamless functional system. The scope of the SI role shall include the interoperable integration of the Health Information Exchange activities as described in State Medicaid Directors letter #16-003 into the Medicaid enterprise."

206. On or about January 1, 2021, NC contracted with KPMG for Systems Integration.

207. Through information and belief, the Relators believe the contract was terminated before KPMG delivered on the terms of the agreement

PRAYER

WHEREFORE, *qui tam* Plaintiff-Relators William Morehead and Rhonda Keyes-Morehead pray for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 *et. seq*
2. That this Court enter a judgment jointly and severally against Defendants in an amount equal to three times the amount of

damages the United States has sustained because of Defendants' actions, plus a civil penalty as defined by 20 U.S.C. § 1234i(2) as adjusted by the Attorney General of the United States of America.

3. Relators William Morehead and Rhonda Keyes-Morehead be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act.

4. That Relators, William Morehead and Rhonda Keyes-Morehead be awarded all costs of this action, including attorney's fees and expenses; and

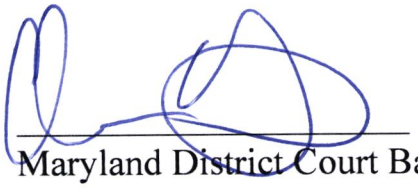
5. That Relators William Morehead and Rhonda Keyes-Morehead recover such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues of fact and damages stated herein.

This the 19th day of August, 2024.

By:



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